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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,293	08/24/2001	Emad S. Alnemri	480140.465	2539

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/16/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,293	ALNEMRI, EMAD S.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-33 and 36-51* is/are pending in the application.

4a) Of the above claim(s) *32-33,40-43 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-31,36-39 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 28-31, 36-39 and 44-47 are examined in the instant application.

REJECTION UNDER 35 USC 112 FIRST PARAGRAPH, SCOPE

Claims 36-39, 44-47 remain rejected under 35 USC 112, first paragraph for lack of enablement for a Smac polypeptide or peptide comprising an amino acid sequence of at least "seven" contiguous amino acid residues from at least residues 56-139 of SEQ ID NO:19, and of which up 183 contiguous amino acid residues can be from residues 56-239 of SEQ ID NO:19, wherein said Smac polypeptide or peptide is capable of specifically binding to at least "any portion" of an Inhibitor of Apoptosis protein.

Applicant argues that the specification discloses two functional domains within the Smac polypeptide, both of which are capable of binding to IAP and promoting caspase activity, e.g. the first seven residues of mature Smac and a second region requiring at least a portion of residues 22-139. Applicant further argues that the method of producing and screening variants are well known and routine in the art.

Applicant's arguments in paper No:13 has been considered but are found not to be persuasive for the following reasons:

It is noted that residues 56-139 of SEQ ID NO:19 is equivalent to residues 1-84 of mature Smac.

The specification discloses that the first 7, 30 or 39 N-terminal residues of mature Smac are able to promote caspase-3 activation (p.43, paragraph before last), and that the caspase-promoting acitivity of Smac resides within an approximately 30 residue-long at its N-terminus (p.43, last paragraph bridging p.44).

The specification further discloses that Smac 15-35 (SEQ ID NO:10) is almost inactive in promoting caspase-3 activation (p.45).

It is noted the claims are not limited to the first 7, 30 or 39 N-terminal residues of mature Smac. The claims encompass an amino acid sequence of at least "seven" contiguous amino acid residues of "any position" from at least residues 56-139 of SEQ ID NO:19, and of which up 183 contiguous amino acid residues can be from residues 56-239 of SEQ ID NO:19, wherein said Smac polypeptide or peptide is capable of specifically binding to at least "any" portion of an Inhibitor of Apoptosis protein.

It is unpredictable that the claimed amino acid sequence comprising seven contiguous amino acids form "any position" from at least residues 56-139 of SEQ ID NO:19, such as the region of Smac 15-35 (SEQ ID NO:10) is capable of specifically binding to at least a portion of an Inhibitor of Apoptosis protein, because as disclosed in the specification not any region of residues 56-139 of SEQ ID NO:19, which is equivalent to residues 1-84 of Smac, is capable of activating caspase-3. For example, Smac 15-35 (SEQ ID NO:10) is almost inactive in promoting caspase-3 activation, wherein interacting with the BIR1/BIR2 domain of XIAP is necessary for inhibition of caspase-3 and caspase-7, and a weak activity of Smac is due to altered interaction with

XIAP (specification, p.42, second paragraph, p.43, first paragraph, p.44, second paragraph and p.45, first paragraph) .

Further, it is well known in the art that a specific binding of a ligand to a substrate requires specific interaction between the ligand and the substrate, and correct conformation of the ligand to fit into the binding site of the substrate, e.g. specific binding between a ligand and a receptor, or between an antigen and an antibody. Thus one cannot predict that at least any seven amino acids from the amino acids 56-139 of SEQ ID NO:19 would have the necessary conformation for specifically binding to the BIR1/BIR2 domains of XIAP.

REJECTION UNDER 35 USC 102(e)

Claims 28, 36, 44 remain rejected under 35 USC 102(e) as being anticipated by US 6,110691 for reasons already of record in paper No:12. Claims 29-31, 37-39, and 45-47 are rejected for the same reasons.

It is noted that claims 29-31, 37-39, and 45-47 were inadvertently not recited in previous Office action. It is clear that claims 29-31, 37-39, and 45-47 should have been included in the rejection, because binding to BIR or BIR1 or BIR2 is an inherent property of the claimed polypeptide of claims 28, 36, 44.

Applicant argues that the 691' patent does not teach or suggest any fragments of the Smac polypeptide, and does not even recognize the Smac polypeptides bind IAP. Applicant asserts that the claims have been amended to recite polypeptide having up to 183 contiguous residues of Smac, thus excluding full length mature Smac polypeptide.

Applicant's arguments in paper No:13 has been considered but are found not to be persuasive for the following reasons:

It is noted that as written the language "up to 183 contiguous amino acid residues of the claimed polypeptide or peptide can be from residues 56-239 of SEQ ID NO:19" encompasses a polypeptide of any length, provided up to 183 contiguous amino acid residues of said polypeptide or peptide can be from residues 56-239 of SEQ ID NO:19

Thus the claims as written encompass a polypeptide any length, provided it comprises at least residues 56-62 of SEQ ID NO:19, and up to 183 contiguous amino acid residues of said polypeptide or peptide can be from residues 56-239 of SEQ ID NO:19, wherein said polypeptide or peptide is capable of specifically binding to at least a portion of an IAP.

The full length Smac polypeptide taught by US 6,110691 certainly comprises at least residues 56-62 of SEQ ID NO:19, and up to 183 contiguous amino acid residues of said polypeptide or peptide can be from residues 56-239 of SEQ ID NO:19.

In addition, although US 6,110691 does not teach that the Smac polypeptides bind IAP, However, the claimed peptide or polypeptide appears to be the same as the prior art polypeptide. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to

establish patentable diffrences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

July 14, 2003